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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/574,252	11/28/2006	David John Chapman-Jones	51407/P029US/10605267	9077
29053 7590 07/01/2011 FULBRIGHT & JAWORSKI L.L.P 2200 ROSS AVENUE SUITE 2800 DALLAS, TX 75201-2784			EXAMINER PATEL, SHEFALI DILIP	
			ART UNIT 3767	PAPER NUMBER
			NOTIFICATION DATE 07/01/2011	DELIVERY MODE ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

doipdocket@fulbright.com

Office Action Summary	Application No.	Applicant(s)	
	10/574,252	CHAPMAN-JONES, DAVID JOHN	
	Examiner	Art Unit	
	SHEFALI PATEL	3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 June 2011.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 26 and 29-39 is/are pending in the application.
- 4a) Of the above claim(s) 34 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 26, 29-33 and 35-39 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on June 2, 2011 has been entered.

Acknowledgments

2. In the reply, filed on June 2, 2011, Applicant amended claim 29.
3. Applicant cancelled claim 48.
4. In the final rejection of January 7, 2011, Examiner noted that the incorrect status identifier (Previously presented) was provided for withdrawn claim 34. Applicant amended claim 34 with the correct status identifier (Withdrawn). The amendment is now compliant.
5. Currently, claims 26, 29-33, and 35-39 are under examination.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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7. Claim 29 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In regards to claim 29, the new limitation of constantly “and concurrently” varying the value of the amplitude of the alternating current “and the frequency of the alternating current” does not appear to be supported by the Specification. In Table 1, at steps 10 and 11, the amplitude remains fixed at 50 μ A while the frequency varies from 10 to 900 Hz. Therefore, it is unclear how the amplitude is constantly and concurrently (i.e. at the same time) varying with the frequency at steps 10 and 11.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 26, 29-32, 35, and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lin-Hendel (US 7,167,752), and further in view of Voznesensky et al (US 6,567,696).

In regards to claim 29, Lin-Hendel teaches a device (Figure 7) for treating damaged tissue, the device comprising:

- a. a dressing (conductive gel-pads) having a treatment surface for applying to a treatment area of said damaged tissue (column 4, lines 59-62)(column 5, lines 4-8)

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- b. a pair of electrodes (coil shaped electrodes) affixed to said treatment surface of the dressing (column 5, lines 4-8)
- c. a control unit (clock [76], processor [77], data memory [78], and program memory [79]) for passing alternating current to the treatment area via the electrodes and for constantly and concurrently varying the value of the amplitude of the alternating current and the frequency of the alternating current to electrically stimulate and repair said damaged tissue (column 4, lines 54-64)(top figure of Figure 8B)

Lin-Hendel does not teach that the pair of electrodes are affixed on said treatment surface of the dressing, since Lin-Hendel teaches that the pair of electrodes are imbedded in the dressing (column 5, lines 4-8). Voznesensky et al teaches a device (Figure 3), wherein a pair of electrodes (electrodes [18]) are both affixed on a treatment surface of a dressing (heat transfer area [16] with dielectric layers [20]) and imbedded in the dressing. It would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify the pair of electrodes, of the device of Lin-Hendel, to also be affixed on the treatment surface of the dressing, as taught by Voznesensky et al, so that thermally the electrode surfaces act as a continuation of the dressing (column 6, lines 36-40), and it has been held that rearranging parts of an invention involves only routine skill in the art. *In re Japikse*, 86 USPQ 70.

In regards to claim 26, in a modified device of Lin-Hendel and Voznesensky et al, Lin-Hendel teaches that the control unit and the dressing are integrated with each other (Figure 7).

In regards to claim 30, in a modified device of Lin-Hendel and Voznesensky et al, Lin-Hendel does not teach that the alternating current is varied between 50 and 500 microamps, as Lin-Hendel teaches that the alternating current is varied between a few mAmps to up to 200

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mAmps (column 6, lines 57-58). But it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify the alternating current to be varied between 50 and 500 microamps, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

In regards to claim 31, in a modified device of Lin-Hendel and Voznesensky et al, Lin-Hendel does not teach that the frequency of the alternating current is varied between 10 and 900 hertz, since Lin-Hendel teaches that the frequency is varied between 0.5 and 200 hertz (column 6, lines 50-52). But it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify the frequency to be varied between 10 and 900 hertz, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

In regards to claim 32, in a modified device of Lin-Hendel and Voznesensky et al, Lin-Hendel is silent about whether the time period between each variation of amplitude is 0.1 s. However, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify the time period between each variation of amplitude to be 0.1 s, since it has been held that discovering the optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

In regards to claim 35, in a modified device of Lin-Hendel and Voznesensky et al, Lin-Hendel teaches that the control unit comprises a housing (clinical device [70]) and electronic circuitry [76][77][78][79][701] in the housing connected to the pair of electrodes (Figure 7)

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In regards to claim 36, in a modified device of Lin-Hendel and Voznesensky et al, Lin-Hendel teaches that the electronic circuitry comprises memory [79] storing at least one program for determining the amplitude, frequency, and waveform of alternating current supplied to the electrodes (column 4, lines 54-64)(column 13, lines 41-42).

10. Claim 33 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lin-Hendel and Voznesensky et al, as applied to claim 29 above, and further in view of Fleming (US 5,891,182).

In regards to claim 33, in a modified device of Lin-Hendel and Voznesensky et al, Lin-Hendel is silent about whether the alternating current has a ramp waveform. Fleming teaches a device for treating tissue, wherein an alternating current has a ramp waveform. It would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify the alternating current, of the modified device of Lin-Hendel and Voznesensky et al, to have a ramp waveform, as taught by Fleming, as the ramp up or soft start of the current applied to the patient will allow the patient to become quickly acclimated to the application of the current through the electrodes without undue surprise to the patient (column 7, lines 42-45).

11. Claims 37 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lin-Hendel and Voznesensky et al, as applied to claim 36 above, and further in view of Fischell et al (US 2002/0099412).

In regards to claims 37 and 38, in a modified device of Lin-Hendel and Voznesensky et al, Lin-Hendel teaches that the control unit comprises an i/o port (input [73] and output [74]) connected to the electronic circuitry; however, Lin-Hendel is silent about whether an external device, such as a wireless transceiver, can connect to the control unit via the i/o port and update

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the memory and control operation of the control unit. Fischell et al teaches a device comprising an i/o port connected to the electronic circuitry, such that an external device can wirelessly connect to the control unit via the i/o port and update the memory and control operation of the control unit (paragraphs [0170] [0171]). It would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify the i/o port, of the modified device of Lin-Hendel and Voznesensky et al, to connect to an external device such as a wireless transceiver, as taught by Fischell et al, as such will allow the i/o port to wirelessly receive physician commands from the physician's external equipment and will read and send back disorder event related data previously stored in the memory back to the physician's external equipment (paragraph [0170] [0171]).

12. Claim 39 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lin-Hendel and Voznesensky et al, as applied to claim 35 above, and further in view of Claude (US 4,982,742).

In regards to claim 39, in a modified device of Lin-Hendel and Voznesensky et al, Lin-Hendel does not teach a removable tab including a metallic strip that connects the electrodes and only allows current to pass once the tab is removed. Claude teaches a device (Figures 1-5) wherein a removable tab (pull away tab [52]) is electro- mechanically connected between a power source [50] and a ground point on the control unit [28]. When the tab [52] is intact, the power source [50] is connected to ground point and energization of the control unit [28] does not occur. Once the tab is removed, the electrical connection between the power source [50] to ground point is broken, and as result, the power source [50] drives the control unit [28] to generate current toward the electrodes (column 3, lines 37-45). It would have been obvious to a

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person having ordinary skill in the art at the time the invention was made to modify the modified device, of Lin-Hendel and Voznesensky et al, with a removable tab, as taught by Claude, as the removable tab will provide a means for controlling the energization of the control unit to allow for or prevent delivery of current to the electrodes (column 3, lines 37-45). Further, Claude is silent about whether the removable tab [52] is metallic. But it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify the removable tab to include a metallic material, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416. Also, it is common knowledge to those of ordinary skill in the art to choose a material that has sufficient conductivity, such as a metal, in electrical energy applications.

Response to Arguments

13. Applicant's arguments filed June 2, 2011, have been fully considered but they are not persuasive:

In regards to claim 29, Applicant argues that Lin-Hendel does not disclose constant variation of both amplitude and frequency (Reply, pages 5-6). Examiner disagrees. Lin-Hendel teaches alternating electrical pulses with varying amplitude and frequency (column 4, lines 54-58) and constant and concurrent variation of amplitude and frequency at least in the top figure of Figure 8B. It can be seen in the last three wave sections of the top figure of Figure 8B that as amplitude increases, frequency also increases. Hence, Lin-Hendel teaches that amplitude and frequency constantly vary and also vary concurrently, or at the same time.

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In regards to claim 29, Applicant argues that the conductive gel pads of Lin-Hendel cannot be properly construed as a dressing having a treatment surface since they provide no protection to a wound or to tissue that has been damaged through trauma (Reply, pages 6-7). Examiner disagrees. Lin-Hendel teaches that the conductive gel pads are placed on skin areas above a set of Acu-points or other Points that treat certain undesirable health conditions and/or help obtain desirable health conditions (column 4, lines 59-62). Hence, since the conductive gel pads are placed on skin area above points that treat undesirable health conditions, they would provide a protecting function to a damage tissue.

In regards to claim 29, Applicant argues that Lin-Hendel does not describe a treatment surface for applying to a treatment area of damaged tissue (Reply, page 7). Examiner disagrees. Lin-Hendel teaches that the conductive gel pads are placed on skin areas above a set of Acu-points or other Points that treat certain undesirable health conditions and/or help obtain desirable health conditions (column 4, lines 59-62). Hence, since the conductive gel pads are placed on skin area above points that treat undesirable health conditions, they are applied to a treatment area of damaged tissue.

In regards to claim 29, Examiner agrees that the coil-shaped electrodes of Lin-Hendel are embedded within the conductive gel pads (Reply, pages 7-8), and hence would not meet the new limitation of electrodes being affixed on the treatment surface of the dressing. However, Examiner has applied a secondary reference of Voznesensky et al to the Lin-Hendel reference in a new grounds of rejection which renders obvious electrodes affixed on a treatment surface of a dressing. Further, Applicant argues that the electrodes of Lin-Hendel pass a magnetic field through the pads. However, Lin-Hendel teaches electrical and/or electromagnetic treatment

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(column 4, lines 54-64), wherein electromagnetic fields have both electric and magnetic field components.

In regards to claim 29, Applicant argues that Lin-Hendel is not concerned with repair of damaged tissue (Reply, page 8). Examiner disagrees. Lin-Hendel teaches restoring proper circulation and health to injured muscle tissue (column 3, lines 34-58).

In regards to claim 26, Applicant argues that Lin-Hendel does not teach that the control unit and the dressing are integrated with each other (Reply, page 9). Even though Lin-Hendel does not show the conductive gel pads in Figure 7, Lin-Hendel does show outputs [74] that are connected to the control unit [76][77][78][79]. These outputs are connected to the conductive gel pads. Since, the control unit, outputs, and conductive gel pads are all connected to each other, it can be said that they form a single, integrated structure.

In regards to claim 30, Applicant argues that the mere fact that the Lin-Hendel device may be operated with any current between a few mAmps and 200 mAmps does not teach constantly varying the alternating current between 50 and 500 microamps (Reply, pages 9-10). However, Examiner never interpreted Lin-Hendel in such a manner. Lin-Hendel teaches that amplitude can be constantly varied (column 4, lines 54-58)(top figure of Figure 8B), but only teaches current between a few mAmps and 200 mAmps. *In re Aller*, 105 USPQ 233 teaches that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. That is to say Applicant's claimed range of amplitude between 50 and 500 microamps can be arrived at by routine skill in the art.

In regards to claim 31, Applicant argues that the mere fact that the Lin-Hendel device may be operated using electrical current between 0.5 Hz and 200 Hz does not teach constantly

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varying the alternating current between 10 and 900 hertz. However, Examiner never interpreted Lin-Hendel in such a manner. Lin-Hendel teaches that frequency can be constantly varied (column 4, lines 54-58)(top figure of Figure 8B), but only teaches current between 0.5 Hz and 200 Hz. *In re Aller*, 105 USPQ 233 teaches that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. That is to say Applicant's claimed range of frequency between 10 and 900 hertz can be arrived at by routine skill in the art.

In regards to claim 32, Applicant argues that Examiner has not established why one skilled in the art would attempt to vary the time period in order to arrive at the claim limitation where the time period between each variation of amplitude is 0.1 s. Instead, the Examiner has merely used the current disclosure about varying amplitude to assert that one skilled in the art could optimize and arrive at the time period recited in the claim. Using the current application as the roadmap for rejecting its claims is inappropriate (Reply, page 10). Examiner disagrees. First, Lin-Hendel does teach that amplitude can be constantly varied and shows time periods with different amplitude (column 4, lines 54-58)(top figure of Figure 8B), but Lin-Hendel is silent about whether the time period is 0.1 s. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980) teaches that discovering the optimum value of a result effective variable involves only routine skill in the art. That is to say Applicant's claimed time period of 0.1 s can be arrived at by routine skill in the art. Second, in response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of

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ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). Lin-Hendel clearly shows in Figure 8B that there is a time period between amplitude variation.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHEFALI PATEL whose telephone number is (571)270-3645. The examiner can normally be reached on Monday through Thursday from 8am-5pm Eastern time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin C. Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Shefali D Patel/

/Theodore J Stigell/

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Examiner, Art Unit 3767
06/28/2011

Primary Examiner, Art Unit 3763